



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-D-0939]

Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act;

Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled “Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” This draft guidance describes FDA’s interpretation of, and policies concerning, the statutory prohibition on wholesaling for certain compounded drugs. This draft guidance also describes examples of how FDA intends to apply the statutory wholesaling provision.

DATES: Submit either electronic or written comments on the draft guidance on or before

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]

to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Please note that late, untimely filed comments will not be

considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS

AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The

<https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m.

Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN

THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for

written/paper submissions) will be considered timely if they are postmarked or the delivery

service acceptance receipt is on or before that date.

ADDRESSES: You may submit comments on any guidance at any time as follows.

### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2023-D-0939 for "Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act." Received comments will be placed in the docket and, except for those submitted as

“Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:  
<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001

New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dominic Markwordt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5104, Silver Spring, MD 20993, 301-796-3100, [Dominic.Markwordt@fda.hhs.gov](mailto:Dominic.Markwordt@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

## I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act.” This draft guidance describes FDA’s interpretation of, and policies concerning, the prohibition on wholesaling in section 503B of the FD&C Act (21 U.S.C. 353b). This draft guidance also describes examples of how FDA intends to apply section 503B of the FD&C Act’s wholesaling provision.

Section 503B of the FD&C Act describes the conditions that must be satisfied for human drugs compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and section 582 (21 U.S.C. 360eee-1) (concerning drug supply chain security requirements).

Pursuant to section 503B(a)(8) of the FD&C Act, one of the conditions that must be met for a drug compounded by an outsourcing facility to qualify for the exemptions in section 503B of the FD&C Act is that the drug will not be sold or transferred by an entity other than the outsourcing facility that compounded the drug. However, the wholesaling provision does not prohibit administration of a drug in a health care setting or dispensing a drug pursuant to a

prescription executed in accordance with section 503(b)(1) of the FD&C Act. The statutory prohibition on wholesaling in section 503B(a)(8) of the FD&C Act helps to ensure that compounding is based on individual patient need, which, in turn, reduces the overall risk of patient harm and helps to preserve the integrity of the U.S. drug approval process. It also helps to preserve the integrity of the U.S. drug supply chain. This prohibition, like other conditions in section 503B of the FD&C Act, preserves important distinctions between outsourcing facilities, which are intended to compound drugs for patients whose medical needs cannot be met by approved drugs, from conventional manufacturers, which generally engage in mass manufacturing of FDA-approved drug products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the "Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act." It does not establish any rights for any person and is not binding on FDA or the public. An alternative approach than what is described in the guidance can be used if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

While this draft guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 207 pertaining to registration of producers of drugs and listing of drugs in commercial distribution have been approved under OMB control number 0910-0045. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice have been approved under OMB control number 0910-0139. The collections of information pertaining to postmarketing adverse drug experience reporting have been approved under OMB control number 0910-0230.

The collections of information for adverse event reporting and human drug compounding under section 503B of the FD&C Act have been approved under OMB control number 0910-0800.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs> or <https://www.regulations.gov>.

Dated: June 23, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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